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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/544,683	04/07/2000	Antonius Arnoldus Christiaan Jacobs	99471 US	1432

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EXAMINER
PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
1645	29

DATE MAILED: 08/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/544,683	JACOBS ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *24 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-7,9,10 and 12-18* is/are pending in the application.

4a) Of the above claim(s) *4-7,10 and 12-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-3,9,18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-7,9-10,12-18 are pending.

Claims 1-3, 9, and 18 are under consideration.

Claims 4-7,10,12-17 stand withdrawn from consideration.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 6, 2003, has been entered.

Rejections Maintained

3. Claims 1-3 , 9 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Cawthraw et al (1994, reference of record), as previously applied to claims 1-3, for reasons of record in paper number 6, paragraph 12.

Response to Arguments

4. The rejection of claims 1-3 , 9 and 18 under 35 U.S.C. 102(b) as being anticipated by Cawthraw et al (1994, reference of record), is traversed on the grounds that the claims are directed to vaccine compositions that "consist essentially of an effective amount of chicken antiserum raised against a flagellaless Campylobacter strain" and the compositions are "substantially free of anti-flagellar antibodies".

5. It is the position of the examiner that the claims are unclear, (see rejection under 35 U.S.C. 112, second paragraph below), that the vaccine antiserum permit the presence of additional antibodies as long as the basic and novel characteristic of the composition which is a vaccine against Campylobacter is preserved, and the antiserum contains antibodies directed against three antigens on a Western blot of 97, 60 and 13 kD. The antiserum of Cawthraw et al contained antibodies that reacted with bands of 97, 60 and 13 kD on a Western blot, were chicken antibodies, functioned as a vaccine. The reference still anticipates the instantly claimed invention.

Claim Rejections - 35 U.S.C. § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-3, 9 and 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-3, 9 and 18 are directed to compositions of chicken antiserum, the antiserum being immunoreactive with bands of about 97+/-5, 60+/-5 and 13+/-3 kD on a Western blot, the source of the antigen in the Western blot not being specifically recited in the claim, and the composition additionally is defined to be "substantially free of anti-flagellar antibodies".

Upon consideration of the disclosure of the instant specification, the specification teaches that antibodies to the about 97+/-5, 60+/-5 and 13+/-3 kD only induce antibodies in the absence of flagella: "[T]hese three proteins apparently only induce antibodies if the flagella is absent, page 4, paragraph 2, lines 14-15). The specification describes compositions that comprise antibodies to the three recited antigens of about 97+/-5, 60+/-5 and 13+/-3 kD, with any flagellar antibodies and compositions that comprise anti-flagellar antibodies (see instant specification at page 2, lines 29-31 and page 3, lines 31-41) but the instantly claimed invention does not exclude the presence of anti-flagella antibodies by reciting of the phrase "substantially free", the phrase "substantially free of anti-flagellar antibodies" does not exclude the presence of anti-flagella antibodies, but a substantial portion of the antibody composition must not be anti-flagella antibodies. The instantly claimed composition of antibodies is not described or disclosed in the instant specification at page 4, paragraph 2.

Additionally the teachings of Guerry (1997), with respect to Campylobacter antigens, discloses that Campylobacter produces two flagella associated antigens of about 97+/-5 and 60+/-5 kD (see page S123, col. 1, Table 1). Two of the three antigens recited in the claims read on protein antigens of Campylobacter that are flagella antigens, specifically flagella hook protein and the flagella subunit of the flagellar filament. With 2 of 3 of the recited antigens in the Western blot reading on Campylobacter antigens that make up flagella, the claimed antibodies would be a composition of antibodies that is NOT substantially free of anti-flagella antibodies as a majority of the antibodies would immunoreact with flagellar antigens.

The combination of claim limitations now recited does not evidence original descriptive support in the instant specification, and therefore recite New Matter.

9. Claims 1-3, 9 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1, 9 and 18 recite the phrase "substantially free"; the phrase "substantially free" sets forth a relative meaning that has not been defined in the instant specification, nor has it been defined in the claims; and the amount of anti-flagellar antibodies in the claimed vaccine composition is not distinctly claimed.

Claims 1-3, 9 and 18 are directed to chicken antiserum vaccines that do not exclude the presence of anti-flagella antibodies. The antiserum is functionally defined through

immunoreactivity with Campylobacter antigens, the 97 kD and 60 kD antigens reading on flagella associated antigens (see Guerry, Journal of Infectious Diseases, 1997, page S123, Table 1). While the vaccines are defined as a product by process composition through the recitation of the phrase "raised against a flagellaless Campylobacter strain (claims 1-3 and 18)" or "antibodies against a flagellaless mutant", the claims also recite additional claim limitations that define the compositions to include antibodies to antigens that make up flagella "wherein the antiserum recognizes a 97 (+/-5 kD), 60 (+/-5 kD) and 13 (+/-3 kD) band (see Guerry, Journal of Infectious Diseases, 1997, page S123, Table 1). No specific antigen source is required as a source of the Western blot antigen, no specific structure or biological functions are required for the recited 97 (+/-5 kD), 60 (+/-5 kD) and 13 (+/-3 kD) bands, and the claimed compositions to not exclude the presence of anti-flagellar antibodies through the recitation of the phrase "substantially free", thus permitting the presence of flagellar antibodies. The 97 kD and 60 kD antigens read on antigens associated with Campylobacter flagella, defining the majority of the antibodies in the claimed compositions to be immunoreactive with flagellar antigens; the claimed compositions therefore are Not "substantially free" of anti-flagellar antibodies as the majority of the antibodies are flagella associated antigens. The invention is not distinctly claimed as the combination of claim limitations contradict each other.

Claim Rejections - 35 U.S.C. § 102

10. Claims 1-3, 9 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Cawthraw et al (1994, reference of record).

Cawthraw et al disclose chicken antibody compositions (see abstract), raised to the parent strain for R2 (see Materials and Methods, bacterial strains), comprised antibodies directed to Campylobacter jejuni (hyper immune chicken serum, see page 344, col. 2, paragraph 2).

The antibodies in the antiserum recognized the about 97 kDa, 60 kDa and 13 kDa bands (see Figures 3, frame B, A, C and D) and Figure 2) and the presence of flagellar antibodies would not change the basic and novel characteristic as the chicken antibodies are directed to Campylobacter jejuni disease associated antigen, and serve to enhance the effectiveness of the claimed vaccine compositions.

The claims do not exclude the presence of antibodies to flagella, but only positively recite the presence of three antibodies which must be present and immunoreact with Campylobacter. The antibodies of Cawthraw et al are taught to provide passive immunization protection (page 348, col. 1, first paragraph). Clearly the composition of Cawthraw et al, though made by a different process than the process limitation recited in the claim, "raised against a flagellaless Campylobacter strain", anticipates the instantly claimed invention, as evidenced by the disclosure of the document which describes a vaccine antiserum composition of chicken antibodies which provided protection against infection, and was raised to the parental strain of Campylobacter of strain R2. The parent strain of strain R2 would therefore produce the same or equivalent antigens

produced by strain R2, and would therefore induce antibodies to the same or equivalent antigens produced by Campylobacter strain R2. The reference anticipates the instantly claimed invention.

11. Claims 1-3, 9 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsubokura et al (June 1997, reference cited in Applicant instant specification, see page 2, lines 28-36) in light of Logan et al (1982)

Tsubokura et al disclose a vaccine composition of an antiserum that consisted essentially of Campylobacter antibodies. Inherently the vaccine of Tsubokura et al, which contained chicken antibodies directed against Campylobacter surface associated antigens which provided protection against challenge by reducing colonization of bacteria by 99% contained the antibodies of the instantly claimed inventions as the vaccines of Tsubokura et al were protective against challenge. (See attached abstract). In light of Logan et al, the anti-Campylobacter antiserum of Tsubokura et al would inherently comprise antibodies directed to Campylobacter antigen of 92 kD (see Logan et al, page 901, col. 1, middle of column and shown in figure 2B, lane 2).

The reference is silent with respect to Western blotting immunoreactivity, but the composition provided protection against challenge and therefore contained protective antibodies which functioned as a vaccine and would therefore be directed against the recited antigens of the claims. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or

of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

12.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

August 19, 2003

LYNETTE R. F. SMITH
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